K982676

OCT 29 1998

510(k) Summary (as per 21CFR807.92) July 31, 1998

Submitter and Contact Person:

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ENACT Health Management Systems, Inc.
1975 El Camino Real, Suite 306
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(650) 967-0379
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Trade Name:

AirWatch II Zone

Common Name:

Peak Flow Meter

Classification Name:

Peak-flow meter for spirometry (as per 21CFR868.1860)

Predicate Device:

ENACT Products, Inc. AirWatch Monitor (K941226)

Description of Device:

The AirWatch II Zone is a pocket-sized, personal electronic device which monitors respiratory status by measuring peak expiratory flow (PEF) rate in liters per minute and forced expiratory volume in one second (FEV1) in liters.

The AirWatch II Zone includes an LCD for displaying PEF and FEV1 information to the consumer, three control buttons, a removable mouthpiece, and an RJ-11C telephone connector which can be used to transfer data stored in the AirWatch to a remote computer.

Indications for Use:

AirWatch II Zone is a medical instrument which is intended to be used for the monitoring of asthma and other chronic respiratory diseases. The instrument measures both Peak Expiratory Flow (PEF) and Forced Expiratory Volume-One Second (FEV1). The instrument is designed for use by consumers from 5 years of age to adults.

Summary of Technological Characteristics:

There is one technological difference between the AirWatch II Zone and its predicate device, the addition of an effort check warning feature.

The technique required to perform a peak expiratory flow rate measurement is effort dependent. Poor technique can result in measurements which do not accurately represent airway status. The AirWatch II Zone checks every measurement with three effort check tests. Warning symbols appear on the display when a measurement fails any one or more of these tests. The appearance of the warning symbols will alert the consumer that the monitor has detected a measurement of suspect quality as a result of poor technique.

The AirWatch II Zone also differs from its predicate device by conforming to the new American Thoracic Society 1994 Standards versus the 1987 Standards.

Summary of Non-Clinical Performance Data:

The AirWatch II Zone and its predicate device meet all applicable electrical, mechanical and environmental performance requirements given in the Reviewers Guidance for Premarket Notification Submissions, Appendix A.

The AirWatch II Zone and its predicate device also conform to the National Asthma Education Program's Statement on Technical Standards for peak flow meters. The AirWatch II Zone meets the American Thoracic Society 1994 Standards for accuracy, precision, linearity, and back pressure. The predicate device meets the American Thoracic Society 1987 Standards.

Summary of Clinical Performance Data:

The AirWatch II Zone was tested on 20 study subjects in each of the following studies: Validation/Measurement Quality Study; Home Use Study; User Guide Study; and Quick Reference Guide Study.

In summary, the Validation/Measurement Quality Study demonstrated that the AirWatch II Zone can appropriately provide information regarding a subject's PEF and FEV1 measurements and can appropriately identify PEF measurement of suspect quality. Other studies demonstrated that consumers can safely and effectively use the AirWatch II Zone under conditions of actual use; that consumers can interpret the AirWatch II Zone's display readings and take appropriate actions; and that the Quick Reference Guide, User Guide, AirWatch II Zone's physical design, and other human factors characteristics are appropriate for consumers.

Technical Specifications:

- Dimensions: L x 4.00 in, W x 2.56 in, D x 0.93 in.
- Weight: 3.3 oz.
- Temperature Range: 41°F to 104°F (5°C to 40°C)
- Storage Temperature: -4°F to 140°F (-20°C to 60°C)
- Operating Humidity: 0% to 95%, non-condensing
- Display: LCD Display

• Power:	Two Type CR2032 3-Volt lithium Batteries
• Battery Symbol:	Low Battery
• Battery Life:	Approximately 1 year with an average daily usage of 3 test sessions per day
• Automatic Turn-Off Period:	30 to 90 seconds, depending on display mode
• Test Session Memory Capacity:	480 test sessions (maximum)
• Memory Life With Batteries Removed or While Battery Drawer Is Open:	2 minutes (minimum)
• Telephone Connector:	Type RJ-11C (standard household jack)

E982676

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 1998

Mr. James Lyon
ENACT Health Management Systems, Inc.
1975 El Camino Real, Suite 306
Mountain View, CA 94040-2218

Re: K982676
AirWatch II Zone
Regulatory Class: II (two)
Product Code: 73 BZH
Dated: July 31, 1998
Received: July 31, 1998

Dear Mr. Lyon:

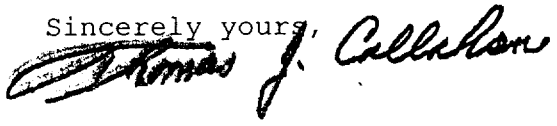
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982676

Device Name: AIRWATCH II ZONE

Indications For Use:

AirWatch II Zone is a medical instrument which is intended to be used for the monitoring of asthma and other chronic respiratory diseases. The instrument measures both Peak Expiratory Flow (PEF) and Forced Expiratory Volume-One Second (FEV1). The instrument is designed for use by consumers from 5 years of age to adults.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number_____

ATTACHMENT B